Future Goals of Engineering in Biology and Medicine

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ARTIFICIAL INTERNAL ORGANS • I

Michael E. De Bakey

The area of artificial internal organs has been one of rapidly increasing interest in the past ten years. It now includes a wide spectrum of topics, and I have decided to focus upon an aspect of it that I regard as basic to the future development of the areas as a whole: the tissue interface problem. The current situation is such that until we have solved the interface problem our approach to a variety of objectives will be impeded. In this light I would like to make some observations on approaches to this problem and to discuss certain aspects of it from our own experience as well as that of others.

There are two general approaches that have been used. One is the development of a nonthrombogenic surface. This has to do particularly with the blood interface problem, and I might note that while there are certainly differences relative to blood interface and other tissue interface problems, both have to be considered with respect to any artificial internal organ. The other approach is the stimulation and development of an autologous tissue interface. We have been concerned particularly with this latter approach, and this has stemmed largely from our own experience with the implantation of artificial arteries.

I would like to mention an instance in which an interesting experiment was inadvertently done. A patient had a Teflon graft implanted that subsequently became occluded. It was removed except for a distal segment. This segment was cleaned out and a replacement graft of Dacron was attached to it. This remained in the patient for four years and was subsequently removed when the patient sud-

denly developed a lesion of this bypass graft. On examination of the specimen it was found that the Dacron surface was perfectly clean and had viable tissue overlying it. This tissue was very thin and it was possible to see the Dacron through it, as it tended to be somewhat transparent. On the other hand, the surface over the Teflon portion of the bypass was fibrinous and it was not adherent to the Teflon. Additionally, there was no tissue adherent to the outside of the Teflon portion of the graft, in contrast to the ingrowth that had occurred in the Dacron portion.

I believe that this brings out clearly, and by example, the nature of one aspect of the interface problem in artificial internal organs. Clearly the use of Dacron instead of Teflon is a step forward in the resolution of the interface problem in this particular instance. It accents the need to concentrate on the development of polymers that will have the special design characteristics required for a variety of tissue interfaces.

The interface problem also emerges as serious in the development of any kind of artificial heart pump. Operating on the evidence that Dacron does provide a stimulus for the growth of autogenous tissue, we have been investigating the properties of a Dacron velour. Microscopic examination of this material reveals that its surface is made up of a number of fine Dacron loops. The purpose of this arrangement is to provide a mesh stratum (loops) that will optimize the opportunity for the development of a proper autogenous tissue interface over a period of time. Experimentation with this Dacron velour as a lining for the pump's diaphragm during prolonged pumping revealed that it produced a fine smooth surface after a two week period of pumping.

This is quite encouraging and is a definite step in the direction of elaboration of a satisfactory long-term implantable pump. The question of course at this time is whether or not over a longer period of time this will provide a permanent, satisfactory autogenous tissue lining.

As far as artificial valves are concerned, the same problem exists. There have been various types of valves introduced in the past five years, but all have been associated with the complication of thrombus formation. In our laboratory we have developed a valve that is similar to ones developed in other laboratories, but it has been developed with the idea of producing an autogenous tissue covering. The problem here of course lies at the flexing joint. These valves have been implanted in animals that were subsequently sacrificed, and we found that all surfaces of the valves are completely covered with a very

smooth lining of autogenous tissue so that they are no longer thrombogenic. Valves with this covering are now being used clinically in our institution and elsewhere.

As I have indicated, the interface problem is also an important one for other artificial internal organs. We have also developed an artificial tendon for direct implantation. The same type of approach is used, i.e., Dacron-backed material that hopefully will become firmly adherent. If successful, these could be attached to a prosthetic device on a limb. As others have, we also have been trying to develop artificial skin, using a similar approach. When this skin is removed many months after an experimental procedure on animals one finds that tissue grows under the artificial skin and loosens without the development of sinus tract formation or infection. In another instance of the interface problem an artificial steel stump covered with Dacron fabric has been implanted in the limb of a horse as a medullary pin. It is hoped that this will provide a strong attachment and at the same time prevent sinus track formation. Examination of cross-sectional views to date has shown that after six weeks the medullary pin has become firmly adherent. It is also quite clear that in this instance there are mechanical aspects to the problem that still have to be resolved. Thus experimentation has just begun in several areas on this type of problem and the results are awaited with considerable interest.

It is apparent that there is increasing interest in artificial organs in many centers throughout the country and that there are a number of biological as well as mechanical problems to be solved (including power sources and control mechanisms). I have taken this opportunity to comment on one aspect of the problem that is common to the spectrum of interests included under the heading of "artificial internal organs," namely, the interface problem. I believe that at present the need for moving this whole field ahead is of primary importance.